

Message Text

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TO AMEMBASSY NICOSIA

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E.O. 11652: N/A

TAGS: TBIO, BDIS, CY, US

SUBJECT: CYPRUS COMPLAINT OF SUB-STANDARD DRUGS

REF: NICOSIA 2147

1. THE GOC CHIEF PHARMACIST HAS ADVISED THE FDA THAT THEIR ANALYSIS OF VARIOUS DRUG PRODUCTS SHIPPED TO THEM BY ALLIED BIOCHEMICAL CO., INC., SAN FRANCISCO HAVE SHOWN THESE DRUGS TO CONTAIN FROM LITTLE TO NONE OF THEIR RESPECTIVE ACTIVE INGREDIENTS.

2. GOC REPORTS THE DRUG SHIPMENTS WERE ACCOMPANIED BY "FREE SALES CERTIFICATES" ISSUED BY THE CITY:COUNTY OF SAN FRANCISCO. THESE CERTIFICATES INCLUDE A STATEMENT THAT THE PRODUCTS WERE MANUFACTURED BY ALLIED AND CONFORM TO THE REQUIREMENTS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT. THESE CERTIFICATES MAY BE FORGERIES.

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3. FDA HAS BEGUN AN INVESTIGATION AND ANTICIPATES THAT IT WILL

BE SOME TIME BEFORE COMPLETION. ONE PROBLEM WHICH ADDS TO THE DELAY IS THE RELATIONSHIP OF VARIOUS FIRMS WHICH MAY BE INVOLVED IN THE SHIPMENTS TO CYPRUS. FDA BELIEVES THE FOLLOWING FIRMS HAVE A RELATIONSHIP TO EACH OTHER, EITHER BY COMMON AGENTS OR BY CORPORATE STRUCTURE:

- ALLIED BIOCHEMICAL CO. INC.
- AMERICAN CHEMICAL AND DRUG CO.
- YARON LABORATORIES
- AMERICAN TRANSPACIFIC CORPORATION
- MALCOLM GREGG
- MICHAEL GORDON
- FORTUNATE PILGRIM

4. AMERICAN CHEMICAL AND DRUG IS CURRENTLY UNDER COURT INJUNCTION WHICH PROHIBITS THEM FROM SHIPPING PAX, A DRUG CONTAINING CHLORDIAZEPOXIDE. ALLIED BIOCHEMICAL INSISTS THEY HAVE NOT SHIPPED MENSANNON (REPORTED BY GOC TO BE VOID OF ACTIVE INGREDIENT CHLORDIAZEPOXIDE) FROM U.S. TO CYPRUS, BUT RATHER HAD THE PRODUCT SHIPPED DIRECTLY TO CYPRUS FROM ITALY. THERE IS AN INDICATION THAT ALLIED SHIPPED CHLORDIAZEPOXIDE TO AMERICAN CHEMICAL AND DRUG IN HONG KONG.

5. FDA NEEDS INFORMATION FROM CYPRUS TO AID IN THIS INVESTIGATION. SPECIFICALLY, WOULD LIKE TO OBTAIN

- COPIES OF ANY AND ALL DOCUMENTS AND CORRESPONDENCE RELATING TO SALE OF DRUGS TO CYPRUS AND THE ISSUANCE OF CERTIFICATES OF SALE COVERING SUCH DRUGS BY

ANY OF THE FIRMS LISTED IN PARAGRAPH E. DOCUMENTS THAT MAY SHOW ORIGIN OTHER THAN THE U.S. SHOULD BE INCLUDED. FDA REALIZES SOME DOCUMENTS HAVE ALREADY BEEN FORWARDED, BUT ASKS THAT THESE BE RESENT WHICH WILL ASSURE THAT FDA HAS ALL THE DOCUMENTS AND NONE WERE LOST IN TRANSIT.

- PHYSICAL SAMPLES OF ALL DRUG PRODUCTS OFFERED BY THE LISTED FIRMS WHICH HAVE BEEN FOUND TO BE DEFECTIVE. THESE SAMPLES MAY BE SMALL, I.E., AS FEW AS A DOZEN TABLETS OF EACH. FDA INTERESTED IN RECEIVING THE LABELS AND ALL ACCOMPANYING LITERATURE FOR THE LIMITED OFFICIAL USE

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PRODUCTS.

6. SHOULD THE INVESTIGATION SHOW THE FIRM(S) ENGAGED IN ILLEGAL ACTIVITIES, THE SAMPLES MAY BE NECESSARY FOR AN ACTION IN COURT. THEREFORE, FDA REQUESTS THAT THE SAMPLES BE SENT DIRECTLY TO U.S. FOOD AND DRUG ADMINISTRATION
50 FULTON ST.-RM 518
SAN FRANCISCO, CALIF. 94102;

THAT THEY BE SHIPPED IN A PACKAGE WHICH HAS BEEN SEALED IN A MANNER WHICH WILL MAINTAIN THE INTEGRITY OF THE PACKAGE DURING SHIPMENT; AND, THE SAMPLES BE ACCOMPANIED BY AN AFFIDAVIT FROM A RESPONSIBLE INVOLVED INDIVIDUAL IN CYPRUS. THE AFFIDAVIT SHOULD INCLUDE

- IDENTITY OF AFFIANT, INCLUDING HIS POSITION AND ASSOCIATION WITH THE SAMPLE.
- A STATEMENT DETERMINING HOW THE AFFIANT KNOWS THE SOURCE OF THE SAMPLE(S).
- A STATEMENT OF HOW THE ORIGINAL SHIPMENT WAS HANDLED BY CYPRUS FROM TIME OF RECEIPT UNTIL THE TIME THE SAMPLE WAS COLLECTED.
- A STATEMENT OF HOW THE SAMPLE WAS SEALED AND PACKAGED FOR SHIPMENT TO FDA
- NECESSARY STATEMENTS TO IDENTIFY ALL LABELS SUBMITTED WITH THE SAMPLES

7. FDA WOULD APPRECIATE ASSISTANCE OF EMBASSY IN OBTAINING THIS INFORMATION AND SUGGESTS THAT CHIEF PHARMACIST, MINISTRY ON HEALTH MIGHT WISH TO BECOME INVOLVED. INGERSOLL

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